From: Charlie Brown [mailto:charlie=toxicteeth.org@mcsv155.net] **On Behalf Of** Charlie Brown
Sent: Tuesday, January 04, 2011 12:30 PM
To: Charles
Subject: FDA scientific panel urges partial ban on amalgam

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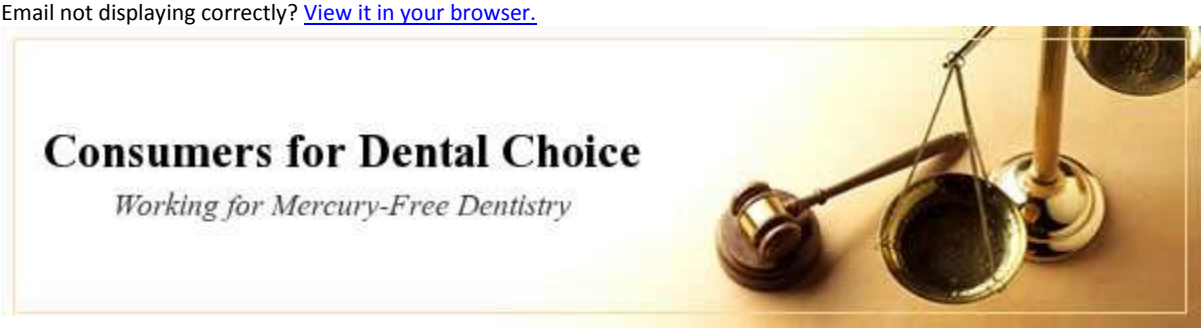

Scientists urge FDA to stop amalgam use in children, pregnant women, and hypersensitive

At the end of the two-day hearing to evaluate the safety of amalgam, FDA's own scientific panel – including neurologists, toxicologists, epidemiologists, and environmental health specialists – told the agency to stop amalgam use in children, pregnant women, and hypersensitive populations.

After reviewing the available scientific studies and the presentations of researchers, experts, dentists, and injured consumers, the scientists concluded that – contrary to the claims of FDA's in-house dentist Susan Runner – amalgam is **not** safe for everybody. According to the panel, FDA's amalgam risk assessments were not adequate to protect hypersensitive adults, children, and unborn babies. Repeatedly, panel members expressed their concern about amalgam use in children. Pediatric neurologist Dr. Suresh Kotagal of the Mayo Clinic summed it up for the entire panel: **"There is really no place for mercury in children."** Other panelists went on to explain that dental mercury is like lead. The panel urged FDA to quickly contraindicate amalgam for these vulnerable populations and insisted that FDA provide consumers with labeling containing clear warnings.

The press heard the scientists loud and clear. According to the well-respected trade publication FDA Webview, the panelists "suggested the agency should ban the device's use in children and pregnant women." * Reuters announced that "Use of fillings in kids, pregnant women biggest concern…Enough uncertainty surrounds silver-colored metal dental fillings with mercury that U.S. regulators should add more cautions for dentists and patients, a U.S. advisory panel said." **

At the end of the hearing, presiding FDA official Anthony Watson, Director of the Division of Dental Devices, announced that FDA would act quickly in response to concerns raised by the panel. But already FDA is ignoring the scientists. FDA's official summary of the hearings reads like the American Dental Association press release that was issued the day before, simply noting that more research is needed.*** The summary does not even mention the scientists' vocal cry for contraindications and restrictions to

protect vulnerable populations. And even though panelists insisted that FDA has a responsibility to provide clear labeling for consumers, the summary twists their comments to absolve FDA of all responsibility – it claims that the panel only suggested the need for informed consent within the dentist-patient relationship.
We cannot let FDA get away with rewriting history and ignoring the scientists as it has done so many times before. Please write Anthony Watson at anthony.watson@fda.hhs.gov

Tell Mr. Watson of FDA:

- Since FDA's own panel of scientists advise that amalgam should "definitely not" be implanted in children, pregnant women, and hypersensitive people, how soon will you take action to protect these vulnerable populations from this toxin?

- Since **FDA has a duty to tell consumers** that amalgam contains mercury that can damage the neurological systems of unborn babies, children, and hypersensitive populations, when does FDA intend to clearly state this warning on its consumer website and in **consumer labeling**?

- Since Commissioner Hamburg claims FDA is committed to transparency, how does FDA plan to keep the public updated on its progress with regard to the amalgam issue?

Thank you to all who came out to testify at the hearings, participated in the demonstration, and submitted comments to FDA! We've gotten this far, let's keep it up.

-- Charlie
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